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Remarks/Arguments:

Claims 1-17 and 21-35 are pending, with claims 1-17 and 21-30 being withdrawn from consideration pursuant to restriction.

Claims 18-20 are cancelled, without prejudice or disclaimer.

New claim 31 contains the subject matter of claim 18, new claims 32 and 33 contain the subject matter of claim 19, and new claims 34 and 35 contain the subject matter of claim 20, rewritten to more clearly define the invention and, further, by limiting the "one or more substances"—the "activity and/or level" of which is measured—to the "gene coding for human MAGUIN-1 (SEQ ID NO: 1) and/or human MAGUIN-2 (SEQ ID NO: 2)," the "transcription product" of the gene, and the "translation product" of the gene. Still further, the new claims are limited to "Alzheimer's disease." Therefore, the claims no longer recite "fragments, derivatives, or variants"—of human Maguin-1 and human Magiun-2—and no longer recite (broadly) "neurodegenerative diseases."

Claim 18 was rejected under 35 USC 112, first paragraph, for allegedly lacking enablement. Reconsideration is requested, in view of changes to the rejected claim reflected in replacement claims 31 and 32.

According to the statement of rejection (Office Action, page 2) (***emphasis in original***), "the specification" is "enabling for an assay for screening ***candidate*** compounds for neurodegenerative diseases in particular Alzheimer's." The scope of present claims 31 and 32—which replace the

rejected claim—is commensurate with the subject matter found "enabling," as set forth in the statement of rejection.

As indicated above, present claim 31 recites "an assay for screening candidate compounds for a modulator of Alzheimer's disease." Based on applicant's understanding of the statement of rejection, the aforesaid claim language effects a claim scope commensurate with the subject matter considered to be "enabling," in accordance with the statement of rejection.

In view of the foregoing, the rejection of claim 18 under §112, ¶1, for allegedly lacking enablement is overcome. Withdrawal of the rejection appears to be in order.

Claims 18-22 were rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. Reconsideration of the rejection is requested, in view of the changes to the rejected claims reflected in replacement claims 31-35.

According to the statement of rejection (Office Action, page 6) "only polypeptides comprising the amino acid sequence set forth in the SEQ ID NO: 1 and 2 (which encode MAGUIN-1 and 2) . . . meets the written description provision of 35 U.S.C. §112, first paragraph." Applicants submit that the presently claimed subject matter is commensurate with the subject matter that "meets the written description provision," according to the statement of rejection.

As explained above, present claims 31-35—replacing the rejected claims—are limited to the proteins (*i.e.*, polypeptides) having the amino acid sequences of SEQ ID NO: 1 and SEQ ID NO: 2, the DNA encoding each of the proteins, and the RNA transcribing each of the proteins. In other words, as recited in the present replacement claims, the DNA as "gene for coding human MAGUIN-

1 (SEQ ID NO: 1) and/or human MAGUIN-2 (SEQ ID NO: 2)," the RNA as "transcription products of a gene coding for human MAGUIN-1 and/or human MAGUIN-2," and the protein as "translation product of a gene coding for human MAGUIN-1 and/or human MAGUIN-2." Applicants submit that the aforesaid claim language constitutes subject matter reflecting the claim scope that "meets the written description provision" of the statute pursuant to the statement of rejection, as understood by applicants.

For the foregoing reasons, the rejection of claims 18-20 under §112, ¶1, for allegedly failing to comply with the written description requirement, is overcome. Withdrawal of the rejection appears to be in order.

Claim 18 was rejected under 35 USC 102(b) as allegedly anticipated by *J. Pharm. and Exp Therap., 296*, 2001, 216-223 (Donello). Reconsideration is requested, in view of changes to the rejected claim reflected in replacement claims 31 and 32.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis*

added). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

The subject matter of claim 18 is now limited—in accordance with replacement claims 31 and 32—to the specific sequences "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)." Donello does not describe the limitation "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene," on present (replacement) claims 31 and 32.

The "absence" from Donello of a limitation—to "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene"—on present (replacement) claims 31 and 32 "negates anticipation" of the claims by the reference. *Kolster Speedsteel A B*, 230 USPQ at 84. Since each limitation on present claims 31 and 32 does no "identically appear" in the Donello disclosure, the reference cannot anticipate the claims. *Gechter*, 43 USPQ2d at 1032.

For the foregoing reasons, the rejection of claim 18 under §102(b), as allegedly anticipated by Donello, is overcome. Withdrawal of the rejection appears to be in order.

Claim 20 was rejected under 35 USC 102(b) as allegedly anticipated by *JBC, 274*, 1999, 11889-11896 (Yao). Reconsideration is requested, in view of changes to the rejected claim reflected in replacement claims 33 and 34.

The subject matter of claim 20 is now limited—in accordance with replacement claims 33 and 34—to the specific sequences "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID

NO: 2)." Yao (Figure 5, section B) does refer to the C-terminal fragments of Maguin-1 and Maguin-2, GST-Maguin-12, and GST-Maguin-16, respectively. Nevertheless, Yao does not describe the limitation "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene," on present (replacement) claims 33 and 34.

The "absence" from Yao of a limitation—to "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene"—on present (replacement) claims 33 and 34 "negates anticipation" of the claims by the reference. *Kolster Speedsteel A B*, 230 USPQ at 84. Since each limitation on present claims 33 and 34 does no "identically appear" in the Yao disclosure, the reference cannot anticipate the claims. *Gechter*, 43 USPQ2d at 1032.

For the foregoing reasons, the rejection of claim 20 under §102(b), as allegedly anticipated by Yao, is overcome. Withdrawal of the rejection appears to be in order.

Claims 18-20 were rejected under 35 USC 103(a) as allegedly unpatentable over Yao in view of US2002/0045590A1 (Tao). Reconsideration is requested, in view of changes to the rejected claims reflected in replacement claims 31-35.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations

distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

The subject matter of claims 18-20 is now limited—in accordance with replacement claims 31-35—to the specific sequences "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2).". Yao does not support the limitation "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene"—as explained above with respect to the §102(b) rejection based on Yao—on present (replacement) claims 31-35.

Tao does not meet the limitation "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene" on present (replacement) claims 31-35. Tao is relied on, according to the statement of rejection (Office Action, page 9) (emphasis added), for allegedly meeting "the steps of claim 19," but, for identifying "compounds that interfere with the binding of NMDA receptor c-terminus . . . and with nNOS binding," i.e., not for any teaching that meets the limitation "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene" on present (replacement) claims 31-35. Accordingly, Tao provides nothing to cure the fatal defficiency of Yao—by failing to meet the limitation "MAGUIN-1 (SEQ ID NO: 1) and/or

MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene" on present (replacement) claims 31-35.

As explained above, neither Yao nor Tao, taken separately or together, supports the limitation "MAGUIN-1 (SEQ ID NO: 1) and/or MAGUIN-2 (SEQ ID NO: 2)" human protein (i.e., "translation product"), or the "gene" encoding the protein or the "transcription product of the gene" on present (replacement) claims 31-35. Since "the cited references do not support each limitation of [each, new] claim," the rejection under §103(a) over Yao in view of Tao would be "inadequate on its face" if applied against any of present claims 31-35. *Thrift*, 63 USPQ2d at 2008. To establish *prima facie* obviousness of a claimed invention, Since all limitations on present claims 31-35 are neither taught nor suggested by Yao and Tao, the combined teachings of the cited references fail to establish a *prima facie* case of obviousness of the presently claimed invention. *Royka, supra.* , 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *Wilson*, 165 USPQ at 496, "and it is error to ignore specific limitations distinguishing over the [prior art] reference[s]." *Murphy*, 217 USPQ at 481.

For the foregoing reasons, the rejection of claims 18-20 under §103(a), as allegedly unpatentable over Yao in view of Tao, is overcome. Withdrawal of the rejection appears to be in order.

Request for Acknowledgment of Receipt of Foreign Priority Document [35 USC 119]

A claim to foreign priority under 35 USC 119 has been made (inventorship declaration of record) and the certified copy of the priority document provided to the International

Attorney Docket No. P67751US1
Application No. 10/508,343

Bureau—satisfying PCT Rule 17.1(a)—and, thereafter, effectively received by the PTO, from the International Bureau (Form PCT/IB/304, mailed 30 September 2003 by the International Bureau, of record, and Notification of Acceptance, mailed 25 March 2005 by the PTO, of record).

Under MPEP 1893.03(c):

> The stamped copy of the priority document sent to the U.S. Patent and Trademark Office from the International Bureau is acceptable to establish that applicant has filed a certified copy of the priority document. The examiner should acknowledge in the next Office Action that the certified copy of the foreign priority document has been filed.

Accordingly, request is made that the Examiner mark the next Office Action to acknowledge, both, the claim to §119 priority and receipt of the certified copy—by marking the appropriate boxes on the Office Action Summary sheet.

Favorable action is requested.

Respectfully submitted,

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